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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/489,473	01/21/2000	Kazuhisa Matsuda	NISS-049	5891

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EXAMINER
PRATT, CHRISTOPHER C

ART UNIT	PAPER NUMBER
1771	

DATE MAILED: 11/06/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

AS-13

Office Action Summary	Application No.	Applicant(s)	
	09/489,473	KAZUHISA MATSUDA	
	Examiner	Art Unit	
	Christopher C. Pratt	1771	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 October 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-33* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-33* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Response to Amendment

1. Prosecution is reopened for the reasons set forth in the interview summary of paper number 12. Despite this advance, the claims are not found patently distinguishable over the prior art.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 1-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Light et al (5514181) in view of Silver et al (5171273).

Light is concerned with the creation of a membrane for tissue regeneration comprising a nonwoven fabric, a film layer, and a sponge layer (fig. 2). Light teaches the film and sponge layer to be composed of either cross-linked hyaluronic acid or collagen (col. 3, lines 30-36 and 63-65; col. 4, lines 18-20). Light teaches the nonwoven layer to be composed of a number of different materials, but doesn't specifically mention collagen. Light, however, teaches that the nonwoven layer and film may be composed of the same materials (col. 4, lines 64-65). Light also teaches that cross linked collagen fibers are well known in the art and refers to the high strength synthetic fibers taught in Silver (col. 1, lines 35-65).

Silver is concerned with the creation of a tissue graft. Silver teaches the use of synthetic collagen fibers (absract) having applicant's claimed diameter (col. 7, lines 2-5). It would have been obvious to one having ordinary skill in the art at the time the invention was made to use the synthetic collagen fibers of Silver to form the nonwoven layer of Light. The skilled artisan would have been motivated to utilize synthetic collagen fibers by the desire to obtain high-strength combined with beneficial wound healing properties (col. 2, lines 28-45 of Light and col. 2, lines 15-35 of Silver).

Light teaches a lyophilization process (col. 4, lines 2-5).

Light teaches the use of an acid (col. 5, line 14).

With respect to the claimed process limitations, it is the examiner's position that the membrane of light is identical to or only slightly different than the membrane prepared by the method of applicant, because both membranes are constructed of the same materials in a similar structure. Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or an obvious variant from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. *In re Thorpe*, 227 USPQ 964, 966 (Fed. Cir. 1985). The burden has been shifted to the applicant to show unobvious differences between the claimed product and the prior art product. *In re Marosi*, 218 USPQ 289, 292 (Fed. Cir. 1983). The membrane of Light either anticipates or strongly suggests the claimed subject matter. It is noted that if the applicant intends to rely on Examples in

the specification or in a submitted Declaration to show non-obviousness, the applicant should clearly state how the Examples of the present invention are commensurate in scope with the claims and how the Comparative Examples are commensurate in scope with the membrane of light.

With respect to claim 10, Light teaches that the collagen of the film layer is embedded into the nonwoven layer (col. 3, lines 45-50). This would inherently act as a binder. This also reads on applicant's limitation that the nonwoven fabric be surrounded on all sides by a coating.

With respect to applicant's claimed multiple layers, it would have been obvious to a person having ordinary skill in the art at the time the invention was made add additional layers of nonwoven material to the membrane of light, since it has been held that mere duplication of the essential working parts of a device involves only routine skill in the art. ST. Regis Paper Co. V. Bemis co., 193 USPQ 8. Additional layers would increase the absorbency of Light's membrane.

Light teaches applicant's claimed nonwoven thickness (col. 3, line 20).

Silver teaches pressing the collagen material into varying dimensions and thicknesses (col. 11, lines 2-5). It would have been obvious to a person having ordinary skill in the art to compress the layers of Light. Such a modification would have been motivated by the desire to render the material suitable for a variety of different applications.

Light is silent with respect to the bulk density of the nonwoven layer. If the nonwoven layer of Light does not inherently have a bulk density within applicant's

claimed range then it would have been obvious to vary said density. The skilled artisan would have been motivated to vary the density of the material by the desire to optimize the absorbent properties of the material.

With respect to the claimed fiber diameter of claim 16, Silver teaches an upper limit of 60 microns. A person having ordinary skill in the art would have found it obvious to increase the fibers size. Such a modification would have been motivated by the desire to utilize stronger fibers when malleability and ease of manipulation are not needed.

Conclusion

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher Pratt whose telephone number is 703-305-6559. The examiner can normally be reached on Monday - Friday from 7 am to 4 pm.

If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Terrel Morris can be reached on 703-308-2414. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9310 for regular communications and 703-872-9311 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.

CHERYL A. JUSKA
PRIMARY EXAMINER

Christopher C. Pratt
October 28, 2002